

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	10/640,853	Confirmation No.:	9178
Appellant	:	<b>SPARER et al.</b>		
Filed	:	August 13, 2003		
TC/A.U.	:	1618		
Examiner	:	<b>ROGERS, James William</b>		
Docket No.	:	P-10998.00		
Customer No.	:	28390		
Title	:	<b>ACTIVE AGENT DELIVERY SYSTEMS, MEDICAL DEVICES, AND METHODS</b>		

Commissioner for Patents  
**Mail Stop Appeal Brief - Patents**  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REPLY BRIEF**

Sir:

This Reply Brief is presented in support of the Appeal filed September 27, 2010, from the final rejection of claims 89, 91-104, 134-138, and 140-150 of the above-identified application under 37 C.F.R. §§1.113 and 1.191, and in response to the Examiner's Answer dated February 15, 2011 (herein referred to as "Examiner's Answer").

Appellants maintain the arguments presented in Appellants' Appeal Brief submitted November 29, 2010 and submit the following supplementary remarks.

A. Claims 89, 91, 93-104, 134-138, 140, 141, and 143-150 are not anticipated under 35 U.S.C. §102(e) by Sirhan et al. (U.S. 2002/0082679 A1).

In response to the Examiner's Answer, Appellants submit that the Examiner clearly erred in failing to consider properly all of the claimed subject matter. This failure to consider all of the claimed subject matter resulted in basing the present rejections on false premises, as is discussed below.

As an initial matter, Appellants maintain that there is no teaching or suggestion in Sirhan et al. of a method of tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend, with the recited relationships of solubility parameters between the polymers

and active agent, over a period of time, which is not controlled by porosity in the miscible polymer blend. In particular, each of the independent claims explicitly recites a combination of at least the following eight relationships, parameters, and functions that cannot be found in Sirhan et al.:

(1) miscibility of the first and second polymers; (2) diffusivity of each polymer relative to each other and a target diffusivity; (3) a specific upper difference in solubility parameter between the first and second polymers; (4) a specific upper difference in solubility parameter between the active agent and either the first or second polymer; (5) a specific upper swellability of the polymer blend; (6) a specific upper molar average solubility parameter of the polymer blend; (7) specific combinations of polymer chemical classes; and (8) the miscible polymer blend controlling the delivery of the active agent, which is not controlled by porosity in the miscible polymer blend. All of these specifically recited relationships, parameters, and functions further define a subset of combinations of polymers and active agents more specifically than in Sirhan et al. Furthermore, with respect to dependent claims 102 and 148, there is no teaching or suggestion in Sirhan et al. that delivery of the active agent occurs predominantly under permeation control.

Throughout the Examiner's Answer, the Examiner repeatedly admitted the following:

“The Sirhan [document] is silent on the solubility parameter value of the biocompatible polymeric films and the active agent.” (Examiner's Answer, pages 10-11 (emphasis added). *See also* page 12.)

“...Sirhan is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other . . .” (Examiner's Answer, page 11 (emphasis added). *See also* page 12.)

“Sirhan . . . does not describe any method for predicting which polymers would be miscible with each other . . .” (Examiner's Answer, page 11 (emphasis added). *See also* page 12.)

“Clearly as set forth above . . . Sirhan, Whitbourne, [Hossainy] and Atala are silent in regards to solubility parameters . . .” (Examiner's Answer, page 22 (emphasis added).)

“. . . Sirhan, Whitbourne, [Hossainy] and Atala do not describe selecting polymers based upon their solubility parameters . . .” (Examiner’s Answer, page 22 (emphasis added).)

Given that each of the independent claims (e.g., claims 89 and 134) recites, among other things, a method of tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend, with the recited relationships of solubility parameters between the polymers and active agent, the Examiner’s admissions establish that the Examiner failed to consider all of the presently claimed subject matter. To wit, the Examiner has maintained an anticipation rejection despite having admitted that the Sirhan et al. document is silent as to, for example, the recited solubility parameters. Appellants submit that the present rejection based on anticipation must fail.

Appellants submit that, because the Examiner has failed to identify within the disclosure of Sirhan et al. each and every element of independent claims 89 and 134, these claims are not anticipated. In evaluating lack of disclosure regarding an obviousness rejection, the Court of Customs and Patent Appeals has stated that “[s]ilence in a reference is hardly a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow.” *See In re Burt and Walter*, 148 U.S.P.Q. 548, 553 (C.C.P.A. 1966). If silence regarding a particular claim element is insufficient to support an obviousness rejection, it logically must be insufficient to support an anticipation rejection.

Furthermore, for at least the reason that the present claims recite, among other things, specific relationships, parameters, and functions that further define a subset of combinations of polymers and active agents more specifically than in Sirhan et al., Appellants submit that the Examiner’s allegation that “Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters . . . , Sirhan teaches the mixtures of the same polymers and active ingredients as [Appellants’] claimed invention” (Examiner’s Answer, page 4) is false and constitutes a clear error.<sup>1</sup>

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<sup>1</sup> The Examiner also made other clearly erroneous statements equating the polymer combinations of Sirhan et al. and other cited documents with the present claims. For example:

Since the implants described by Hossainy, Whitbourne, Sirhan and Atala teach the same types of polymer blends and active agents it is inherent that the same composition will have the same the same [*sic*] properties including its ability of “tuning” the active agent, the claimed solubility parameter relationships, diffusivity, swellability and release of the active. (Examiner’s Answer, page 18.)

In the Examiner's Answer, as a result of failing to consider all of the claimed subject matter, Appellants submit that the Examiner mischaracterized Sirhan et al., as discussed below, and failed to establish that the Sirhan et al. document anticipates the present claims.

For example, Appellants submit that the Examiner mischaracterized Sirhan et al. for at least the reason that, regarding the selection of first and second polymers and active agent, Sirhan et al. are silent on solubility parameters and using the parameters to select the polymers and actives, as the Examiner admitted. Thus, Sirhan et al. cannot teach or suggest the selection of the first and second polymers and the active agent, as recited in the present claims. Thus, Sirhan et al. cannot anticipate Appellants' claims.

Further, for at least this reason that Sirhan et al. fail to expressly or inherently set forth the specific polymer combinations and active agents recited in the claims, the Examiner cannot base the present rejection on the statement that "Sirhan teaches the mixtures of the same polymers and active ingredients as [Appellants'] claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters" (Examiner's Answer, page 4). The Examiner's premise (i.e., "Sirhan teaches the mixtures of the same polymers and active ingredients" as Appellants' claims) is false. For at least the reason that Sirhan et al. do not "teach[] the mixtures of the same polymers and active ingredients," the Examiner's statement that "it is inherent that the same polymers and actives will have the same solubility parameters" is not applicable to this case with respect to Sirhan et al.

In the Examiner's Answer, the Examiner alleged, "It appears as though [Appellants] are claiming a new and/or undiscovered property of an old composition." (Examiner's Answer, page 4.) The Examiner has again failed to acknowledge that the present claims recite relationships, parameters, and functions that further define a subset of combinations of polymers and active agents more specifically than in Sirhan et al. To clarify the record, Appellants are not "claiming a new and/or undiscovered property of an old composition," as the Examiner alleged. In fact, Appellants are not claiming a composition. Rather, as stated above, Appellants are claiming a method of tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend, wherein

the methods recite the above-discussed combination of at least eight relationships, parameters, and functions, that cannot be found in Sirhan et al.

The Examiner has dismissed the fact that Sirhan et al. disclose more than a dozen classes of suitable polymers listed at paragraphs [0119] and [0120], including “mixtures, copolymers, and combinations thereof” for each set of polymers, resulting in a vast number of individual polymer species and an even larger number of combinations of polymers and active agents. The subsets of polymer and active agent combinations to which Appellants’ claims are drawn is small and specific in relation to all of the possible combinations encompassed by the disclosure of Sirhan et al. and are not disclosed in Sirhan et al. Recently, the Court of Appeals for the Federal Circuit reaffirmed that, for purposes of determining anticipation, “[i]t is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus.” *In re Gleave*, 560 F.3d 1331, 1337 (Fed. Cir. 2009) (quoting *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006)). Moreover, Sirhan et al. provide no teaching or suggestion that would direct one skilled in the art to Appellants’ claimed subset of polymer and active agent combinations from among the innumerable combinations described.

In the Examiner’s response to Appellants’ arguments at pages 18-20 of the Examiner’s Answer, the Examiner apparently alleged that “polymer blends are a well known, old and mature field” for the mere reason that Sirhan et al. “teach and claim numerous polymer blends.” This again dismisses the fact that Sirhan et al. disclose more than a dozen classes of suitable polymers that must be considered in view of the rule reaffirmed in *In re Gleave*, quoted above.

The Examiner alleged, “First with respect to Sirhan . . . the polymer blend described is claimed, all US patents are considered valid, thus there is adequate guidance and direction for the claimed polymers.” (Examiner’s Answer, page 19.) The Examiner’s statement is unclear and/or inapplicable for at least the reason that the Sirhan et al. document is a patent application publication (US 2002/0082679 A1), not a patent. Regardless, the Examiner has failed to identify the guidance and direction from Sirhan et al. to select the subsets of polymer and active agent combinations recited in the present claims.

Application No. 10640853

Reply Brief dated: April 11, 2011

Reply Brief to Examiner's Answer dated February 15, 2011

In the Examiner's Answer, the Examiner alleged, “[A]ppellants argue, contradictory [*sic*], that a prior art reference which is similar to their claimed invention in that it also describes numerous types of polymer blends, does not teach their claimed blend just because numerous combinations are possible.” (Examiner's Answer, page 20.) To clarify the record, Appellants argued that Sirhan et al. disclose more than a dozen classes of suitable polymers at paragraphs [0119] and [0120], including “mixtures, copolymers, and combinations thereof” for each set of polymers. Appellants did not argue that Sirhan et al. “is similar to their claimed invention.” Although Sirhan et al. describe certain classes and/or types of polymers that are identified in Appellants' specification as classes and/or types from which polymers may be selected to form the particular subpopulation of miscible polymer blends recited in Appellants' claims, Appellants submit that the present claims are patentable over Sirhan et al. for the reasons discussed herein.

For at least these reasons, review and reversal by the Board of the 35 U.S.C. §102 rejection based on Sirhan et al. are respectfully requested.

B. Claims 89, 91, 93-104, 134-138, 140, 141, and 143-150 are not anticipated under 35 U.S.C. §102(b) by Hossainy et al. (U.S. Patent No. 6,153,252) or by Whitbourne et al. (U.S. Patent No. 6,110,483) and claims 89, 91-97, 99, 101-103, 134-138, 140-143, 145, and 147-150 are not anticipated under 35 U.S.C. §102(e) by Atala (U.S. Patent No. 6,576,019).

In response to the Examiner's Answer, Appellants submit that the Examiner clearly erred in failing to consider properly all of the claimed subject matter. This failure to consider all of the claimed subject matter resulted in basing the present rejections on false premises, as is discussed below.

As an initial matter, Appellants maintain that there is no teaching or suggestion in any of Hossainy et al., Whitbourne et al., and Atala of a method of tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend, with the recited relationships of solubility parameters between the polymers and active agent, over a period of time, which is not controlled by porosity in the miscible polymer blend. In particular, each of the independent claims explicitly recites a combination of at least eight relationships, parameters, and functions (discussed above in the arguments regarding Sirhan et al.) that cannot be found in any of Hossainy et al., Whitbourne et al., and Atala. All of these specifically recited relationships, parameters, and functions further define a subset of combinations of polymers and active agents more specifically than in any of Hossainy et al., Whitbourne et al., and Atala. Furthermore, with respect to dependent claims 102 and 148, there is no teaching or suggestion in any of Hossainy et al., Whitbourne et al., and Atala that delivery of the active agent occurs predominantly under permeation control.

Throughout the Examiner's Answer, the Examiner repeatedly admitted the following:

The Hossainy patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. (Examiner's Answer, page 13 (emphasis added). See also page 14.)

. . . Hossainy is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other . . . (Examiner's Answer, page 13 (emphasis added). See also page 14.)

[Hossainy] does not describe any method for predicting which polymers would be miscible with each other . . . . (Examiner's Answer, page 13 (emphasis added). *See also* page 14.)

The Whitbourne patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. (Examiner's Answer, page 15 (emphasis added). *See also* page 16.)

. . . Whitbourne is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other . . . . (Examiner's Answer, page 15 (emphasis added). *See also* page 16.)

Whitbourne does not describe any method for predicting which polymers would be miscible with each other . . . . (Examiner's Answer, page 15 (emphasis added). *See also* page 17.)

The Atala patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. (Examiner's Answer, page 8 (emphasis added). *See also* page 9.)

. . . Atala is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other . . . . (Examiner's Answer, page 9 (emphasis added). *See also* page 10.)

Atala does not describe any method for predicting which polymers would be miscible with each other . . . . (Examiner's Answer, page 9 (emphasis added). *See also* page 10.)

Clearly as set forth above . . . Whitbourne, [Hossainy] and Atala are silent in regards to solubility parameters . . . . (Examiner's Answer, page 22 (emphasis added).)

. . . Whitbourne, [Hossainy] and Atala do not describe selecting polymers based upon their solubility parameters . . . . (Examiner's Answer, page 22 (emphasis added).)

Given that each of the independent claims (e.g., claims 89 and 134) recites, among other things, a method of tuning the delivery of an active agent from an implantable medical device to a subject using

a miscible polymer blend, with the recited relationships of solubility parameters between the polymers and active agent, the Examiner's admissions establish that the Examiner failed to consider all of the presently claimed subject matter. To wit, the Examiner has maintained anticipation rejections despite having admitted that each of the Hossainy et al., Whitbourne et al., and Atala documents are silent as to, for example, the recited solubility parameters. Appellants submit that the present rejections based on anticipation must fail.

Appellants submit that, because the Examiner has failed to identify within any of the disclosures of Hossainy et al., Whitbourne et al., and Atala each and every element of independent claims 89 and 134, these claims are not anticipated. As argued above with reference to Sirhan et al., if silence regarding a particular claim element is insufficient to support an obviousness rejection, it logically must be insufficient to support an anticipation rejection. *See In re Burt and Walter*, 148 U.S.P.Q. 548, 553 (C.C.P.A. 1966).

Furthermore, for at least the reason that the present claims recite, among other things, specific relationships, parameters, and functions that further define a subset of combinations of polymers and active agents more specifically than in any of Hossainy et al., Whitbourne et al., and Atala, Appellants submit that each the following allegations by the Examiner is false and constitutes clear error:<sup>2</sup>

Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters . . . , Hossainy teaches the mixtures of the same polymers and active ingredients as [Appellants'] claimed invention. (Examiner's Answer, page 5.)

Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters . . . , Whitbourne teaches the mixtures of the same polymers and active ingredients as [Appellants'] claimed invention. (Examiner's Answer, pages 6-7.)

Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters . . . , Atala teaches the

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<sup>2</sup> The Examiner also made other clearly erroneous statements equating the polymer combinations of Hossainy et al., Whitbourne et al., and Atala (as well as Sirhan et al.) with the present claims. *See, e.g., supra* footnote 1 (Examiner's quoted statement).

mixtures of the same polymers and active ingredients as [Appellants'] claimed invention. (Examiner's Answer, page 8.)

In the Examiner's Answer, as a result of failing to consider all of the claimed subject matter, Appellants submit that the Examiner mischaracterized each of Hossainy et al., Whitbourne et al., and Atala as discussed below, and failed to establish that any of the Hossainy et al., Whitbourne et al., and Atala documents anticipates the present claims.

For example, Appellants submit that the Examiner mischaracterized each of Hossainy et al., Whitbourne et al., and Atala for at least the reason that, regarding the selection of first and second polymers and active agent, each of Hossainy et al., Whitbourne et al., and Atala is silent on solubility parameters and using the parameters to select the polymers and actives, as the Examiner admitted. Thus, none of Hossainy et al., Whitbourne et al., and Atala can teach or suggest the selection of the first and second polymers and the active agent, as recited in the present claims. Thus, none of Hossainy et al., Whitbourne et al., and Atala can anticipate Appellants' claims.

Further, for at least this reason that none of Hossainy et al., Whitbourne et al., and Atala expressly or inherently set forth the specific polymer combinations and active agents recited in the claims, the Examiner cannot base the present rejection on the statement that "Hossainy teaches mixtures of the same polymers and active ingredients as [Appellants'] claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters" (Examiner's Answer, page 5) or similar statements made with regard to Whitbourne et al. (*see* Examiner's Answer, pages 6-7) and Atala (*see* Examiner's Answer, page 8). Each of the Examiner's premises with respect to Hossainy et al., Whitbourne et al., and Atala (e.g., that each of Hossainy et al., Whitbourne et al., and Atala "teaches the mixtures of the same polymers and active ingredients" as Appellants' claims) is false. For at least the reason that none of Hossainy et al., Whitbourne et al., and Atala "teach[] the mixtures of the same polymers and active ingredients" as Appellants' claims, the Examiner's statement that "it is inherent that the same polymers and actives will have the same solubility parameters" is not applicable to this case with respect to any of Hossainy et al., Whitbourne et al., and Atala.

In the Examiner's Answer, the Examiner alleged, "It appears as though [Appellants] are claiming a new and/or undiscovered property of an old composition." (Examiner's Answer, pages 5, 7, and 8.) The Examiner has again failed to acknowledge that the present claims recite relationships, parameters, and functions that further define a subset of combinations of polymers and active agents more specifically than in any of Hossainy et al., Whitbourne et al., and Atala. To clarify the record, Appellants are not "claiming a new and/or undiscovered property of an old composition," as the Examiner alleged. In fact, Appellants are not claiming a composition. Rather, as stated above, Appellants are claiming a method of tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend, wherein the methods recite the above-discussed combination of at least eight relationships, parameters, and functions, that cannot be found in any of Hossainy et al., Whitbourne et al., and Atala.

The Examiner has dismissed the fact that Hossainy et al. disclose over 30 classes of polymers listed at columns 4 and 5, encompassing innumerable species of polymers (arguably thousands if not hundreds of thousands or more). The Examiner has dismissed the fact that Whitbourne et al. teach more than a dozen classes of polymers in columns 5 and 6, which, as in Hossainy et al. (discussed herein above), include innumerable species of polymers. The Examiner has dismissed the fact that Atala discloses a vast number of individual polymer species. The subset of polymer and active agent combinations to which Appellants' claims are drawn is small and specific in relation to all of the possible combinations encompassed by the disclosure of any of Hossainy et al., Whitbourne et al., and Atala and is not disclosed in any of Hossainy et al., Whitbourne et al., and Atala. Recently, the Court of Appeals for the Federal Circuit reaffirmed that, for purposes of determining anticipation, "[i]t is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus." *In re Gleave*, 560 F.3d 1331, 1337 (Fed. Cir. 2009) (quoting *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006)). Moreover, none of Hossainy et al., Whitbourne et al., and Atala provide a teaching or suggestion that would direct one skilled in the art to Appellants' claimed subset of polymer and active agent combinations from among the innumerable combinations described.

In the Examiner's response to Appellants' arguments at pages 18-20 of the Examiner's Answer, the Examiner appears to allege that "polymer blends are a well known, old and mature field" for the mere reason that the cited documents "teach and claim numerous polymer blends." This again dismisses the facts that Hossainy et al., Whitbourne et al., and Atala disclose classes of polymers encompassing a vast numbers of polymer species, wherein such facts must be considered in view of the rule reaffirmed in *In re Gleave*, quoted above.

In the Examiner's Answer, the Examiner alleged, "[A]ppellants argue, contradictory [sic], that a prior art reference which is similar to their claimed invention in that it also describes numerous types of polymer blends, does not teach their claimed blend just because numerous combinations are possible." (Examiner's Answer, page 20.) To clarify the record, Appellants argued that Hossainy et al., Whitbourne et al., and Atala disclose classes of polymers that encompass innumerable polymer species. Appellants did not argue that any of Hossainy et al., Whitbourne et al., and Atala "is similar to their claimed invention." Although each of Hossainy et al., Whitbourne et al., and Atala describe certain types of polymers that encompass at least some of the polymers from which polymers of Appellants' miscible polymer blend may be selected, Appellants submit that the present claims are patentable over Hossainy et al., Whitbourne et al., and Atala for the reasons discussed herein.

For at least these reasons, review and reversal by the Board of the 35 U.S.C. §102 rejections based on each of Hossainy et al., Whitbourne et al., and Atala are respectfully requested.

C. Claims 89, 91, 93-104, 134-138, 140, 141, and 143-150 are not unpatentable under 35 U.S.C. §103(a) over any of the following combinations of cited documents: (1) Sirhan et al. (U.S. 2002/0082679 A1) in view of Van Krevelen (*Properties of Polymers*, 3<sup>rd</sup> ed., Chapter 7, 189-225); (2) Sirhan et al. in view of Coleman et al. (*Specific Interactions and the Miscibility of Polymer Blends*, Ch. 2; *A Practical Guide to Polymer Miscibility*, 1991; 49-156); (3) Hossainy et al. (U.S. Patent No. 6,153,252) in view of Van Krevelen; (4) Hossainy et al. in view of Coleman et al.; (5) Whitbourne et al. (U.S. Patent No. 6,110,483), in view of Van Krevelen; and (6) Whitbourne et al. in view of Coleman et al.; and claims 89, 91-97, 99, 101-103, 134-138, 140-143, 145, and 147-150 are not unpatentable under

35 U.S.C. §103(a) over (7) Atala (U.S. Patent No. 6,576,019) in view of Van Krevelen or (8) Atala in view of Coleman et al.

Appellants maintain that neither Van Krevelen nor Coleman et al. provide that which is missing from each of Sirhan et al., Hossainy et al., Whitbourne et al., and Atala.

The Examiner alleged, “Appellants believe that the inventiveness of their claimed invention stems from the fact that like dissolves like, a well known and old scientific principle.” (Examiner’s Answer, page 21.) Appellants have not made such a statement. Thus, the Examiner’s statement is false and mischaracterizes Appellants’ arguments, as discussed below.

The relevant disclosure of each of Sirhan et al., Hossainy et al., Whitbourne et al., and Atala for analysis of the present rejections is this -- each of Sirhan et al., Hossainy et al., Whitbourne et al., and Atala identify polymer classes (e.g., more than a dozen in each of Sirhan et al. and Whitbourne et al., and over 30 classes in Hossainy et al.) encompassing a vast number of individual polymer species. Furthermore, neither of the other documents (Van Krevelen and Coleman et al.) provides that which is missing from Sirhan et al., Hossainy et al., Whitbourne et al. and Atala. Van Krevelen and Coleman et al. each merely teaches general theories about solubility parameters and predicting miscibility. Neither Van Krevelen nor Coleman et al. cures the deficiencies of any of Sirhan et al., Hossainy et al., Whitbourne et al., and Atala or provides sufficient teaching or suggestion to select the combination of components recited in Appellants’ claims, especially with respect to the identification of the specific combinations of polymers and active agents according to the recited combination of at least eight relationships, parameters, and functions enumerated herein above.

Appellants submit that while the cited combinations of documents describe classes of polymers that encompass at least some of the polymers from which polymers used to form the miscible polymer blends in Appellants’ claims may be selected, the combinations neither teach nor suggest the selection criteria for the recited combinations of polymers and active agents. The cited combinations of documents provide no blaze marks that would direct one skilled in the art to select polymers and active agents based on their miscibility and/or the recited differences in solubility parameter, and/or the other explicitly recited relationships, parameters, and functions.

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With regard to guidance from Sirhan et al., the Examiner alleged, “[T]he polymer blend described is claimed, all US patents are considered valid, thus there is adequate guidance and direction for the claimed polymers since they are in fact claimed.” Appellants reiterate that this statement is unclear and/or inapplicable for at least the reason that the Sirhan et al. document is a patent application publication, not a patent.

The Examiner alleged, “[Appellants’] remarks seem to only point out that guidance is not provided in the primary reference when the rejections were made in combination with the secondary references Van Krevelen and Coleman.” (Examiner’s Answer, page 22.) Again, the Examiner has mischaracterized Appellants’ arguments. As stated above, cited combinations of documents do not teach or suggest the selection criteria for the recited combinations of polymers and active agents and the cited combinations of documents provide no blaze marks that would direct one skilled in the art to select polymers and active agents based on their miscibility and/or the recited differences in solubility parameter, and/or the other explicitly recited relationships, parameters, and functions.

The Examiner alleged that “[w]hile the [E]xaminer notes the case law [of *KSR Int'l Co. v. Teleflex Inc. (KSR)*, 82 USPQ2d 1385 (2007) and *Süd-Chemie Inc. v. Multisorb Techs., Inc.*, 89 USPQ2d 1768 (2009)] the current issue differs from the specific cases.” (Examiner’s Answer, page 16.) However, the Examiner failed to identify how or why the current issue differs from these cases. Appellants maintain that these cases, as well as other cases cited and discussed in Appellants’ Appeal Brief, are directly on point in the present case.

Review and reversal by the Board of all of the 35 U.S.C. §103 rejections are respectfully requested.

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For the foregoing reasons and those presented in Appellants' Appeal Brief, Appellants respectfully request that the Board review and reverse the rejections of claims 89, 91-104, 134-138, and 140-150 as discussed herein and that notification of the allowance of these claims be issued.

Respectfully submitted,

/Anthony A. Sheldon, Reg. No. 47,078/  
Anthony A. Sheldon  
Registration No. 47,078  
Attorney for Appellants

Medtronic Vascular, Inc.  
3576 Unocal Place  
Santa Rosa, CA 95403  
Facsimile No.: (707) 543-5420